

**SMARTMOUTH MOUTH SORE ZINC ACTIVATED FORMULA- menthol,
unspecified form
Triumph Pharmaceuticals Inc.**

**SmartMouth™ Mouthwash
Mouth Sore Zinc Activated Formula**

Drug Facts

Active Ingredient

Menthol 0.2% (when mixed as directed)

Purpose

Oral Pain Reliever

Uses

For the temporary relief of occasional minor irritation, pain, sore mouth, and sore throat.

For the temporary relief of pain associated with:

- Canker sores
- Minor dental procedures
- Minor irritation or injury of the mouth or gums
- Minor irritation of the mouth and gums caused by dentures or orthodontic appliances

Warnings

Do not use this product for more than 7 days unless directed by a dentist or healthcare provider

When using this product do not swallow

- do not exceed recommended dosage

Stop use and see your physician promptly if

- swelling, rash or fever develops
- irritation, pain or redness persists or worsens
- sore mouth symptoms do not improve in 7 days

Keep out of reach of children. If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away

Directions

- **Adults and children 12 years of age & older:** Swish 20mL of rinse (pour to indicator line on cup) around the mouth over the affected area for at least 1 minute, gargle and then spit out. Use up to 4 times daily or as directed by a dentist or doctor.

- **Children 6 years to under 12 years of age** should be supervised in the use of this product.
- **Children under 6 years of age:** do not use.

Inactive Ingredients

Solution 1: Purified Water, Sodium Benzoate, Sodium Chlorite, and Benzoic Acid. Solution 2: Purified Water, Sorbitol, Poloxamer 407, Glycerin, Propylene Glycol, Poloxamer 124, Zinc Chloride, Flavor, Sodium Benzoate, Benzyl Alcohol, Sodium Saccharin, Peppermint Oil, Benzoic Acid, Aloe Extract, Sodium Chloride, D&C Yellow No. 10, FD&C Blue No. 1

Questions?

1-800-492-7040

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TRIUMPH PHARMACEUTICALS INC.
ST. LOUIS, MISSOURI 63141

PRINCIPAL DISPLAY PANEL - 437 mL Kit Cello Pack

MIXES TO ACTIVATE
2 Powerful Solutions

smart
mouth™

Mouth Sore
Zinc Activated Oral Rinse™

24
HOUR
BAD BREATH
PREVENTION
WITH A MORNING & EVENING RINSE

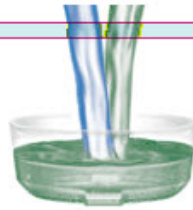
Soothes Oral Pain & Irritation

For all Mouth Sores, Canker Sores and Cheek Bites

Relieves Gum, Braces and Denture Irritation

Zinc Promotes Oral Health & Boosts Immunity

COOL MINT • 16 FL. OZ. (473 mL) • ALCOHOL FREE • SAFE FOR PEOPLE WITH
DIABETES



MIXES TO ACTIVATE
2 Powerful Solutions



Mouth Sore

Zinc Activated Oral Rinse*



**BAD BREATH
PREVENTION**
WITH A MORNING & EVENING RINSE

Soothes Oral Pain & Irritation

For all Mouth Sores, Canker Sores and Cheek Bites
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COOL MINT - 16 FL. OZ. (473 mL) - ALCOHOL FREE - SAFE FOR PEOPLE WITH DIABETES



TO OPEN
Tear Down

← 2mm Art Underlap - background elements only, no critical artwork →

Push Down
Along
Perforated
Lines

WHY 2 SEPARATE SOLUTIONS?

The power of SmartMouth™ is in the ACTIVATION. Pour the two solutions together to activate the Smart-Zinc™, which eliminates and prevents bad breath for at least 12 hours with each rinse.

STORE BOTTLE UPRIGHT. DO NOT SQUEEZE.



STEP 1
Lift cup and spout to remove and discard green spacer and foil seal

STEP 2
Replace cup and spout and push down with palm to secure

STEP 3
Remove cup and pour to line

STEP 4
Rinse, gargle & spit out



NOT FOR TRAVEL AFTER OPENING
Travel Size Options Available at SmartMouth.com

Drug Facts	
Active Ingredient Menthol 0.2% (when mixed as directed)	Purpose Oral Pain Reliever
Uses For the temporary relief of occasional minor irritation, pain, sore mouth, and sore throat. For the temporary relief of pain associated with: - Canker sores - Minor dental procedures - Minor irritation or injury of the mouth or gums - Minor irritation of the mouth and gums caused by dentures or orthodontic appliances	
Warnings Do not use this product for more than 7 days unless directed by a dentist or healthcare provider When using this product do not swallow - do not exceed recommended dosage Stop use and see your physician promptly if - swelling, rash or fever develops - irritation, pain or redness persists or worsens - sore mouth symptoms do not improve in 7 days Keep out of reach of children. If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away	
Directions - Adults and children 12 years of age & older: Swish 20mL of rinse (pour to indicator line on cup) around the mouth over the affected area for at least 1 minute, gargle and then spit out. Use up to 4 times daily or as directed by a dentist or doctor. - Children 6 years to under 12 years of age should be supervised in the use of this product. - Children under 6 years of age: do not use.	
Inactive Ingredients Solution 1: Purified Water, Sodium Benzoate, Sodium Chloride, and Benzoic Acid. Solution 2: Purified Water, Sorbitol, Poloxamer 407, Glycerin, Propylene Glycol, Poloxamer 124, Zinc Chloride, Flavor, Sodium Benzoate, Benzyl Alcohol, Sodium Saccharin, Peppermint Oil, Benzoic Acid, Aloe Extract, Sodium Chloride, D&C Yellow No. 10, FD&C Blue No. 1	
Questions? 1-800-492-7040	Use Immediately After Pouring To Ensure Dual Formula Activation.

PLEASE NOTE: SmartMouth™ is designed to be poured in the forward direction only. To avoid leakage, keep bottle upright and do not squeeze. If spilled on fabric, wash out immediately. Do not use this product if the tamper-evident foil seal is missing or broken. Use within 6 months after opening.

***SATISFACTION GUARANTEE:**

For complete guarantee terms, visit <https://smartmouth.com/satisfaction-guarantee/>

SMARTMOUTH™
ORAL HEALTH LABORATORIES

WWW.SMARTMOUTH.COM
PATENT SMARTMOUTH.COM/PATENTS

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PLEASE RECYCLE



NO ACTIVATION - CLEAN

PRINCIPAL DISPLAY PANEL - 437 mL Kit Cello Pack - Breath Rinse

MIXES TO ACTIVATE
2 Powerful Solutions

smart
mouth™

Mouth Sore
Zinc Activated Breath Rinse™

24
HOUR

**BAD BREATH
PREVENTION
WITH A MORNING & EVENING RINSE**

**Oral Pain Relief For
CANKER SORES & CHEEK BITES
GUM, BRACES & DENTURE IRRITATION**

COOL MINT • 16 FL. OZ. (473 mL) • ALCOHOL FREE

TO OPEN
Tear Down
Along
Perforated
Lines



NOT FOR TRAVEL AFTER OPENING
Find Travel Packs @SmartMouth.com

Drug Facts	
Active Ingredient	Purpose
Menthol 0.2% (when mixed as directed)	Oral Pain Reliever
Uses For the temporary relief of occasional minor irritation, pain, sore mouth, and sore throat. For the temporary relief of pain associated with: • Canker sores • Minor dental procedures • Minor irritation or injury of the mouth or gums • Minor irritation of the mouth and gums caused by dentures or orthodontic appliances	
Warnings Do not use this product for more than 7 days unless directed by a dentist or healthcare provider.	
When using this product do not swallow • do not exceed recommended dosage Stop use and see your physician promptly if • swelling, rash or fever develops • irritation, pain or redness persists or worsens • sore mouth symptoms do not improve in 7 days Keep out of reach of children. If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.	
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Mouth Sore

Zinc Activated Breath Rinse™

24
HOUR

BAD BREATH
PREVENTION

WITH A MORNING & EVENING RINSE

WHY 2 SEPARATE SOLUTIONS?

The power of SmartMouth™ is in the ACTIVATION. Pour the two solutions together to activate the Smart-Zinc™, which eliminates and prevents bad breath for at least 12 hours with each rinse.

✓ Dentist Recommended

✓ Safe For People with Diabetes

QUESTIONS OR COMMENTS?
CALL 1-800-492-7040
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PATENT SMARTMOUTH.COM/PATENTS

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SMARTMOUTH™
ORAL HEALTH LABORATORIES



PRINCIPAL DISPLAY PANEL - 296 mL Kit Cello Pack

**MIXES TO ACTIVATE
2 Powerful Solutions**

smart
mouth™

Mouth Sore

Zinc Activated Oral Rinse™

24

HOUR

BAD BREATH

PREVENTION

WITH A MORNING & EVENING RINSE

Soothes Oral Pain & Irritation

For all Mouth Sores, Canker Sores and Cheek Bites

Relieves Gum, Braces and Denture Irritation

Zinc Promotes Oral Health & Boosts Immunity

COOL MINT • 10 FL. OZ. (296 mL) • ALCOHOL FREE • SAFE FOR PEOPLE WITH
DIABETES



MIXES TO ACTIVATE
2 Powerful Solutions



Mouth Sore

Zinc Activated Oral Rinse*



**BAD BREATH
PREVENTION**
WITH A MORNING & EVENING RINSE


Soothes Oral Pain & Irritation

For all Mouth Sores, Canker Sores and Cheek Bites

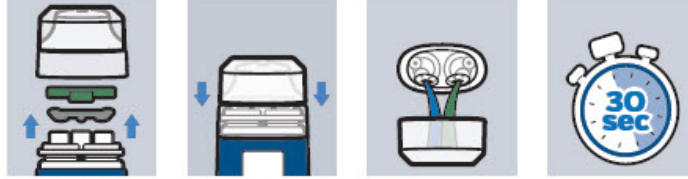
Relieves Gum, Braces and Denture Irritation

Zinc Promotes Oral Health & Boosts Immunity

COOL MINT - 10 FL. OZ. (296 mL) • ALCOHOL FREE • SAFE FOR PEOPLE WITH DIABETES


TO OPEN
 Tear Down
 Along
 Perforated

STORE BOTTLE UPRIGHT. DO NOT SQUEEZE.



STEP 1

Lift cup and spout to remove and discard green spacer and foil seal

STEP 2

Replace cup and spout and push down with palm to secure

STEP 3

Remove cup and pour to line

STEP 4

Rinse, gargle & spit out



NOT FOR TRAVEL AFTER OPENING

Travel Size Options Available at SmartMouth.com

Drug Facts

Active Ingredient	Purpose
Menthol 0.2% (when mixed as directed)	Oral Pain Reliever

Uses For the temporary relief of occasional minor irritation, pain, sore mouth, and sore throat. For the temporary relief of pain associated with:
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Inactive Ingredients Solution 1: Purified Water, Sodium Benzoate, Sodium Chlorite, and Benzoic Acid. Solution 2: Purified Water, Sorbitol, Poloxamer 407, Glycerin, Propylene Glycol, Poloxamer 124, Zinc Chloride, Flavor, Sodium Benzoate, Benzyl Alcohol, Sodium Saccharin, Peppermint Oil, Benzoic Acid, Aloe Extract, Sodium Chloride, D&C Yellow No. 10, FD&C Blue No. 1

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***SATISFACTION GUARANTEE:** For complete guarantee terms, visit <https://smartmouth.com/satisfaction-guarantee/>

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PRINCIPAL DISPLAY PANEL - 320 mL Kit Cello Pack

MIXES TO ACTIVATE
 2 Powerful Solutions

smart
 mouth™

Mouth Sore
Zinc Activated Oral Rinse™

24
HOUR
BAD BREATH
PREVENTION
WITH A MORNING & EVENING RINSE

Soothes Oral Pain & Irritation

For all Mouth Sores, Canker Sores and Cheek Bites

Relieves Gum, Braces and Denture Irritation

Zinc Promotes Oral Health & Boosts Immunity

COOL MINT • 10.82 FL. OZ. (320 mL) • ALCOHOL FREE • SAFE FOR PEOPLE WITH
DIABETES



MIXES TO ACTIVATE
2 Powerful Solutions



Mouth Sore

Zinc Activated Oral Rinse™



**BAD BREATH
PREVENTION**
WITH A MORNING & EVENING RINSE

Soothes Oral Pain & Irritation

For all Mouth Sores, Canker Sores and Cheek Bites

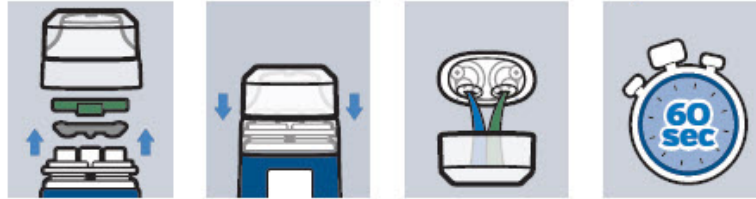
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COOL MINT - 10.82 FL. OZ. (320 mL) - ALCOHOL FREE - SAFE FOR PEOPLE WITH DIABETES


TO OPEN
 Tear Down
 Along
 Perforated
 Lines

STORE BOTTLE UPRIGHT. DO NOT SQUEEZE.



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STEP 2
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Rinse, gargle & spit out



NOT FOR TRAVEL AFTER OPENING

Travel Size Options Available at SmartMouth.com

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SMARTMOUTH MOUTH SORE ZINC ACTIVATED FORMULA
menthol, unspecified form kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76357-409
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76357-409-16	1 in 1 CELLO PACK	01/01/2022	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE, PLASTIC	237 mL
Part 2	1 BOTTLE, PLASTIC	237 mL

Part 1 of 2

SMARTMOUTH MOUTH SORE SOLUTION 1

mouthwashes and breath fresheners (liquids and sprays) [oral products] liquid

Product Information

Route of Administration	DENTAL
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Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
COLR	White ()	
INGR	Water (UNII: 059QF0KO0R)	
INGR	Sodium Benzoate (UNII: OJ245FE5EU)	
INGR	Benzoic Acid (UNII: 8SKN0B0MIM)	
INGR	Sodium Chlorite (UNII: G538EBV4VF)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		01/01/2022	

Part 2 of 2

SMARTMOUTH MOUTH SORE SOLUTION 2

menthol, unspecified form liquid

Product Information

Item Code (Source) NDC:76357-499

Route of Administration DENTAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	10 mg in 20 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Sodium Benzoate (UNII: OJ245FE5EU)	
Benzoic Acid (UNII: 8SKN0B0MIM)	
Glycerin (UNII: PDC6A3C0OX)	
Poloxamer 407 (UNII: TUF2IVW3M2)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Poloxamer 124 (UNII: 1S66E28KXA)	
Zinc Chloride (UNII: 86Q357L16B)	
Sodium (UNII: 9NEZ333N27)	
Saccharin Sodium (UNII: SB8ZUX40TY)	
Sodium Chloride (UNII: 451W47IQ8X)	
Benzyl Alcohol (UNII: LKG8494WBH)	
Sorbitol (UNII: 506T60A25R)	
Aloe Vera Leaf (UNII: ZY81Z83H0X)	
Peppermint Oil (UNII: AV092KU4JH)	

Product Characteristics

Color	GREEN	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a		

Combination Product			
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph drug	M022	01/01/2022	
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph drug	M022	01/01/2022	

SMARTMOUTH MOUTH SORE ZINC ACTIVATED FORMULA
menthol, unspecified form kit

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76357-411

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76357-411-10	1 in 1 CELLO PACK	01/01/2022	

Quantity of Parts		
Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE, PLASTIC	138 mL
Part 2	1 BOTTLE, PLASTIC	138 mL

Part 1 of 2
SMARTMOUTH MOUTH SORE SOLUTION 1
mouthwashes and breath fresheners (liquids and sprays) [oral products] liquid

Product Information	
Route of Administration	DENTAL

Other Ingredients		
Ingredient Kind	Ingredient Name	Quantity

COLR	White ()	
INGR	Water (UNII: 059QF0KO0R)	
INGR	Sodium Benzoate (UNII: OJ245FE5EU)	
INGR	Benzoic Acid (UNII: 8SKN0B0MIM)	
INGR	Sodium Chlorite (UNII: G538EBV4VF)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		138 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		01/01/2022	

Part 2 of 2

SMARTMOUTH MOUTH SORE SOLUTION 2

menthol, unspecified form liquid

Product Information

Item Code (Source)	NDC:76357-491
Route of Administration	DENTAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	10 mg in 20 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Sodium Benzoate (UNII: OJ245FE5EU)	
Benzoic Acid (UNII: 8SKN0B0MIM)	
Glycerin (UNII: PDC6A3C00X)	
Poloxamer 407 (UNII: TUF2IVW3M2)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Poloxamer 124 (UNII: 1S66E28KXA)	
Zinc Chloride (UNII: 86Q357L16B)	
Sodium (UNII: 9NEZ333N27)	

Saccharin Sodium (UNII: SB8ZUX40TY)	
Sodium Chloride (UNII: 451W47IQ8X)	
Benzyl Alcohol (UNII: LKG8494WBH)	
Sorbitol (UNII: 506T60A25R)	
Aloe Vera Leaf (UNII: ZY81Z83H0X)	
Peppermint Oil (UNII: AV092KU4JH)	

Product Characteristics			
Color	GREEN	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		138 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph drug	M022	01/01/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph drug	M022	01/01/2022	

SMARTMOUTH MOUTH SORE ZINC ACTIVATED FORMULA

menthol, unspecified form kit

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76357-410

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76357-410-01	1 in 1 CELLO PACK	01/01/2023	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE, PLASTIC	160 mL
Part 2	1 BOTTLE, PLASTIC	160 mL

Part 1 of 2

SMARTMOUTH MOUTH SORE SOLUTION 1

mouthwashes and breath fresheners (liquids and sprays) [oral products] liquid

Product Information

Route of Administration DENTAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
COLR	White ()	
INGR	Water (UNII: 059QF0KO0R)	
INGR	Sodium Benzoate (UNII: OJ245FE5EU)	
INGR	Benzoic Acid (UNII: 8SKN0B0MIM)	
INGR	Sodium Chlorite (UNII: G538EBV4VF)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		160 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		01/01/2023	

Part 2 of 2

SMARTMOUTH MOUTH SORE SOLUTION 2

menthol, unspecified form liquid

Product Information

Item Code (Source) NDC:76357-490

Route of Administration DENTAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	10 mg in 20 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Sodium Benzoate (UNII: OJ245FE5EU)	
Benzoic Acid (UNII: 8SKN0B0MIM)	
Glycerin (UNII: PDC6A3C0OX)	
Poloxamer 407 (UNII: TUF2IVW3M2)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Poloxamer 124 (UNII: 1S66E28KXA)	
Zinc Chloride (UNII: 86Q357L16B)	
Sodium (UNII: 9NEZ333N27)	
Saccharin Sodium (UNII: SB8ZUX40TY)	
Sodium Chloride (UNII: 451W47IQ8X)	
Benzyl Alcohol (UNII: LKG8494WBH)	
Sorbitol (UNII: 506T60A25R)	
Aloe Vera Leaf (UNII: ZY81Z83H0X)	
Peppermint Oil (UNII: AV092KU4JH)	

Product Characteristics

Color	GREEN	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		160 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph drug	M022	01/01/2023	

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OTC monograph drug	M022	01/01/2023	

Labeler - Triumph Pharmaceuticals Inc. (017853461)

Revised: 12/2023

Triumph Pharmaceuticals Inc.